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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/173,531	10/15/1998	Ralph M. Ellison	7409-150-999	1947

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EXAMINER

PAK, JOHN D

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/173,531

Applicant(s)

ELLISON ET AL.

Examiner

JOHN D PAK

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,10-12,14-17,21-26,28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,10-12,14-17,21-26,28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Applicant was advised in the Office Action of Paper No. 24 that the Finality of the Office Action of Paper No. 20 (3/17/03) was withdrawn. This Office action is pursuant to receipt of the full references mentioned in Paper No. 24. Applicant's amendment of 8/14/03 has been entered.

It is noted claims 22 and 23 have been amended to be identical to claim 21. Appropriate corrections are needed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10-12, 14, 15, 26, 28, 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosner (Acta Neurologica Latinoamericana, vol. 21(1-4), 1975, pp. 126-132).

Rosner explicitly disclose treating brain cancer, intracranial neoplasm in humans (p. 127, see from last paragraph of left column to the first paragraph of right column). To 1000 cc 5% dextrose in saline, 0.06 g of mapharsen, which is an organic arsenic compound, was added to formulate a daily infusion (p. 127, right column, section 2). 0.25 g carbarsone (another organic arsenic compound) in capsule form and Fowler's solution (another arsenic form) are disclosed for oral medication (p. 128, left column, section 3). Radiation therapy "shows the most beneficial effects if given during the

course of arsenical therapy (p. 126, left column, section 4). Several clinical administration of arsenical preparations for treating glioblastoma multiforme are disclosed (see e.g., Case Nos. 4, 5, 6, 10, 11 on pages 128-129).

The claims are thereby anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 16-17, 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosner in view of Repetto et al., CN 1121807, CN 1079391 and JP 51-88620.

Rosner explicitly disclose treating brain cancer, intracranial neoplasm in humans (p. 127, see from last paragraph of left column to the first paragraph of right column). To 1000 cc 5% dextrose in saline, 0.06 g of mapharsen, which is an organic arsenic compound, was added to formulate a daily infusion (p. 127, right column, section 2). 0.25 g carbarsone (another organic arsenic compound) in capsule form and Fowler's solution (another arsenic form) are disclosed for oral medication (p. 128, left column, section 3). Radiation therapy "shows the most beneficial effects if given during the course of arsenical therapy" (p. 126, left column, section 4; see also p. 130, Summary

and Conclusions section). Several clinical administration of arsenical preparations for treating glioblastoma multiforme are disclosed (see e.g., Case Nos. 4, 5, 6, 10, 11 on pages 128-129).

Repetto et al. disclose toxicity of sodium arsenite and sodium arsenate on neuroblastoma cells. See the Results section on pages 146-149; see also the paragraph bridging pages 151 and 152.

CN 1121807 teaches treating liver cancer, as well as leukemia and lymphatic cancer, with a solution formulated with 1-10 g arsenic trioxide, 8 g sodium chloride, and 1000 ml water. 10 ml injection per day is disclosed for adults, with different dosage and concentrations being possible based on age and conditions (translation page 5, last full paragraph). CN 1079391 teaches treating cervical cancer, as well as skin cancer and other "in vivo cancer entities" (translation page 8, lines 3-5) with arsenic compounds. Suspended injection and liposome are used (paragraph bridging translation pages 7-8). JP 51-88620 teaches that a mixture of ferrous, arsenic and sulfate ions can "cure cancerous disease of stomach, duodenum, uterus, lung, pancreas, etc." (see applicant's provided abstract).

The difference between the claimed invention and Rosner is that Rosner does not expressly state that the (i) targeted glioblastoma is metastatic, (ii) the arsenic compound can be used with the other chemotherapeutic agents specified in applicant's claim 16, (iii) administration via an implantation device, and arsenic in the form of

arsenic trioxide, halide, sulfide. However, the combined teachings of the references suggest the same.

Rosner does teach treating metastatic brain cancer (see e.g., p. 130, left column, part 2d). CN 1121807, CN 1079391 and JP 51-88620 disclose the wide-spectrum anticancer activity of various arsenic substances, including arsenic trioxide. Delivery in the form of liposome, as taught by CN 1079391 is within "implantation device" feature. Therefore, one having ordinary skill in the art would have been motivated to utilize various compounds that deliver arsenic to treat solid tumors such as those claimed by applicant, e.g. glioblastoma, including arsenic trioxide, arsenic halide, arsenic sulfide. As for use with other known chemotherapeutic agents such as those recited in applicant's claim 16, one of ordinary skill in the art of treating cancer would have been motivated to combine the efficacy of known anticancer agents in order to obtain their combined benefits. As applicant has acknowledged in the specification that the claim-recited compounds are known chemo-therapeutic agents, their combined use with arsenic compounds would have been fairly suggested.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly suggested by the combined teachings of the cited references.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**, **effective February 3, 2004**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Thurman Page, can be reached on (571)272-0602, effective February 3, 2004.

The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.



JOHN PAK
PRIMARY EXAMINER
GROUP 1600